# HEMOCHRON® Jr. *Signature*

## Whole Blood Microcoagulation System

CE

## Operator's Manual
**English**

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This manual is published by International Technidyne Corporation (ITC) for use with the HEMOCHRON Jr. *Signature* Whole Blood Microcoagulation System.


Questions or comments regarding the contents of this manual can be directed to the address at the back of this manual or to your ITC representative.


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## INTENDED USE

The HEMOCHRON Jr. *Signature* Whole Blood Microcoagulation System is a battery-operated, hand-held instrument that performs individual point-of-care coagulation tests on fresh or citrated whole blood. These tests include: Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate). The system is intended to be used with test cuvettes that are available from ITC.

Data management capabilities are included with the instrument. These capabilities include storage of up to 234 patient results and 85 quality control results, designation of quality control levels, tagging of test results with date and time, entry of Patient ID and/or Operator ID, and printing of results.

HEMOCHRON *ReportMaker*™ software, provided separately, allows the user to connect a personal computer to an instrument and perform various data management and data reporting functions.

For *in vitro* Diagnostic Use.

## SUMMARY AND EXPLANATION

Events that lead to formation of a blood clot are simplified in coagulation theory into two interactive coagulation cascades that are referred to as the **intrinsic** and the **extrinsic** pathways.

The clotting factors involved in these pathways are numbered I through V and VII through XIII. The intrinsic pathway begins with the contact activation of factor XII and, through the interaction of several coagulation factors, results in the conversion of soluble fibrinogen to insoluble fibrin strands. The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Platelets, essential co-factors in this reaction, provide the platelet phospholipid (PF3) surface on which coagulation reactions occur.

Heparin is used to maintain hemostasis during cardiac surgery and percutaneous coronary interventional (PCI) procedures. However, its administration can pose significant risk to the patient since individual patients can vary as much as twelve-fold in heparin sensitivity. Overdosing heparin can result in dangerous bleeding, and underdosing heparin can lead to thrombosis. Therefore, monitoring heparin therapy is vital in guarding against these undesirable side effects.

Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate) tests are general coagulation screening tests that are used to measure the functionality of the blood coagulation cascade. The ACT test is the method of choice for monitoring heparin therapy during cardiac surgery and PCI. Fresh whole blood is added to an activator (Celite®, silica, kaolin, or glass particles), and then timed for the formation of a clot. The type of activator used will affect the degree of prolongation of the ACT to a given heparin dose.

The HEMOCHRON Jr. ACT+ test uses a mixture of silica, kaolin, and phospholipids as an activator to create a rapid and highly sensitive alternative to existing ACT tests. This test demonstrates linearity at heparin concentrations ranging from 1.0 to 6.0 units of heparin per mL of blood, and it is not affected by high dose aprotinin therapy.

The HEMOCHRON Jr. ACT-LR test uses a Celite activator due to its excellent heparin sensitivity. The test demonstrates linearity at heparin concentrations up to 2.5 units of heparin per mL of blood. The test is not intended for use with aprotinin therapy.

The HEMOCHRON Jr. APTT test measures the intrinsic coagulation pathway and involves all coagulation factors except factors VII and III (tissue factor). The APTT test improves the PTT test through use of a contact activating substance, which standardizes activation of Factor XII to provide a more precise and sensitive assay for low level heparin monitoring. The HEMOCHRON Jr. APTT test is formulated to provide optimal heparin sensitivity at heparin concentrations up to 1.5 units of heparin per mL of blood.

The HEMOCHRON Jr. APTT Citrate test performs the same measurement as the APTT test, using a citrated whole blood sample.

The HEMOCHRON Jr. PT test measures the extrinsic coagulation pathway and is sensitive to coagulation factors VII, X, V, II, and fibrinogen. PT results may be abnormal in patients with liver disease or Vitamin K deficiency. The test is widely used to monitor oral anticoagulant therapy. The PT test is a unitized test system utilizing a highly sensitive thromboplastin for improved specificity and sensitivity.

The HEMOCHRON Jr. PT Citrate test performs the same measurement as the PT test, using a citrated whole blood sample.

## PRINCIPLES OF OPERATION

The HEMOCHRON Jr. *Signature* Whole Blood Microcoagulation System provides many features for ease of use and reliability, including a patented clot detection system, a data storage module, interfaces for a laboratory computer and/or printer, and a streamlined user-interface panel.

The system measures whole blood clotting times using HEMOCHRON Jr. disposable single-use cuvettes. Each cuvette contains all of the reagents necessary for a specified test.

The operator inserts a cuvette for the test into the instrument and then enters information about the sample (if desired). After the cuvette has warmed to 37 °C ±1.0 °C, the instrument beeps, signaling the operator that a blood sample can be added to the cuvette and the test started.

The operator then places a drop of blood in the sample well of the cuvette and presses the **START** key. The instrument measures the required volume of blood and automatically moves it into the cuvette test channel, where it is mixed with reagents. The remainder of the blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel on the cuvette.

After mixing with the reagent, the sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation. The test channel is maintained at 37 °C ±1.0 °C during the test.

The rate of movement of the sample is monitored by a series of LED optical detectors that are aligned with the test channel. When the blood clots, the flow of the blood sample within the test channel is impeded, reducing its rate of flow between the optical detectors.

This reduction in flow below a predetermined value signals to the instrument that a clot has formed. The instrument also emits an audible beep when clot formation occurs, indicating the end of the test. An internal timer measures the elapsed time between the start of the test and the clot formation. During the test, the whole blood clotting time (in seconds) is displayed.

APTT and APTT Citrate results are displayed as plasma equivalent (PE) values, and PT and PT Citrate results are displayed as the International Normalized Ratios (INR) and PE values. ACT+ and ACT-LR results are displayed as Celite ACT equivalent time.

The results will remain on the display while the cuvette remains in the instrument.

The result can be automatically printed along with the time and date the test was run, the Patient ID, and Operator ID, if entered. Quality control results can be tagged with the appropriate level (Normal or Abnormal). Up to 234 patient test results and 85 quality control test results can be stored on the instrument for later printing or downloading.

### Definitions and Terms

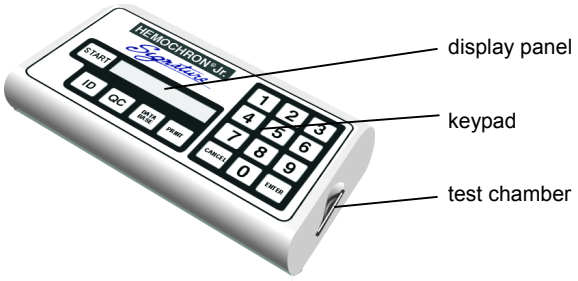
The following acronyms and abbreviations are used in this manual, instrument screens, and printouts:

| | |
|---|---|
| **ACT** | Activated Clotting Time |
| **APTT** | Activated Partial Thromboplastin Time |
| **DB** | Database |
| **EQC** | Electronic System Verification Cartridge |
| **INR** | International Normalized Ratio |
| **LQC** | Liquid Quality Control |
| **OID** | Operator Identification Number |
| **PID** | Patient Identification Number |
| **POCC** | Point of Care Coordinator |
| **PT** | Prothrombin Time |
| **QC** | Quality Control |
| **TQC** | Temperature Verification Cartridge |

## DESCRIPTION

The HEMOCHRON Jr. *Signature* instrument is a hand-held device. It contains a **test chamber** which warms a test cuvette to the required temperature, and it performs all operations to measure the clotting time of a whole blood sample after it is placed in the test cuvette and the test is started by the operator.

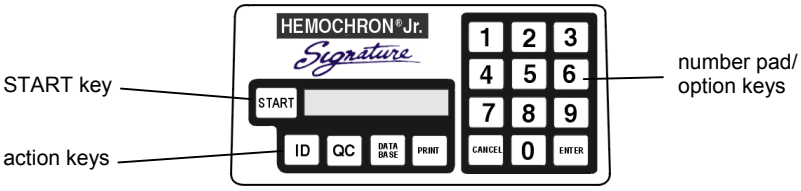
Operator instructions are shown on the **display panel**, and the operator enters commands and information using the **keypad**. When the test is completed, the results are shown on the display panel and stored in system memory for printing or downloading.




### Keypad

The front panel contains a keypad with various action keys as well as a number pad. The operator uses the keypad to select a command or enter information.

**Action keys** display a menu of commands according to the label on the key. For example, the **PRINT** key displays printing commands. **Number pad** (or **option**) keys are used to enter numerals for IDs or selection of commands.




| Key | Purpose |
|---|---|
| **START** | Initiate a test after the test cuvette has reached 37 ±1.0 °C and the sample is added. |
| **ID** | Enter a Patient ID or Operator ID. |
| **QC** | Specify that the QC sample being run is a normal (Level 1) or abnormal (Level 2) control. |
| **DATABASE** | Display the number of patient or QC test results that are currently stored in the instrument and the number of additional test results that can be stored.<br>Delete patient or QC records. |
| **PRINT** | Print results on an external printer for the last test result, patient database, or quality control database. |
| **0** through **9** | Enter numeric information (e.g., a Patient ID, an Operator ID, a time, or a date). |
| **CANCEL** | Cancel an operation and return to the previous state. |
| **ENTER** | Accept a numeric entry (e.g., a Patient ID, an Operator ID, a time, or a date). |

**Display Panel**

The instrument communicates with the operator by means of the display panel. For example, ADD SAMPLE and PRESS START are alternately displayed after a test cuvette reaches 37 ±1.0 °C:

| ADD SAMPLE |
|---|

The display is illuminated to enhance visibility in low light conditions. To conserve power during battery operation, the display is not illuminated when the test well is empty or when a test is running. The display is momentarily illuminated after a key is pressed or when results of a completed test are displayed. While a test is running, the display can be momentarily illuminated by pressing the **CANCEL** or **ENTER** key or any numeric key.

**Menus**

The action keys display the various commands for operating and configuring the system. Display a menu by pressing the corresponding action key. For example, press the **PRINT** key to display the print menu:

| 1=LST 2=PAT 3=QC |
|---|

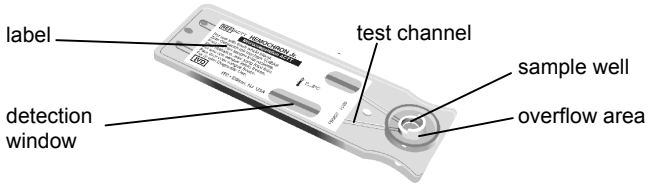
Select the appropriate command by pressing the indicated numeric key. For example, to print the last patient result, select the **1** key.

The commands displayed for each action key are summarized below:

| Menu | | Commands |
|---|---|---|
| **ID** | | 1=PATIENT<br>2=OPER |
| **QC** | | 1=N<br>2=Abn<br>3=Pat |
| **DATA BASE** | (First) | 1=QUERY<br>2=ERASE |
| | (Successive, for QUERY) | 1=PATIENT<br>2=QC |
| | (Successive, for ERASE) | Sure?<br>1=YES<br>2=NO |
| **PRINT** | | 1=LST<br>2=PAT<br>3=QC |

**Test Cuvettes**

Tests are performed with single-use disposable HEMOCHRON Jr. test cuvettes. Each test cuvette contains a **label**, a **sample well**, a **test channel** containing reagents, an enclosed **waste reservoir**, and optical **detection windows**.




The cuvette label is human- and instrument-readable. The current test is automatically read by the instrument and displayed for confirmation when the operator inserts the cuvette into the test chamber. After the cuvette has warmed to 37 ±1.0 °C, ADD SAMPLE and PRESS START are displayed by the instrument, alerting the operator to place a drop of blood in the sample well and begin the test by pressing the **START** key.

***Note**: Refer to the package insert accompanying the HEMOCHRON Jr. test cuvettes for storage and handling instructions.*

**Features**

The HEMOCHRON Jr. *Signature* has a number of performance and convenience features. These are summarized below:

- the system is portable for bedside use
- fresh whole blood or citrated whole blood can be used (assay dependent)
- only one drop of blood is required
- results are available in minutes
- results are displayed appropriately as whole blood, plasma equivalent, Celite equivalent seconds, or INR
- test type is automatically read from the cuvette
- test results are automatically stamped with date and time
- results from 234 patient tests and 85 QC tests can be stored
- stored results can be printed and/or downloaded to a personal computer
- optional entry of Operator ID (OID) or Patient ID (PID)
- optional operator lockout
- instrument self checks are automatically performed
- Electronic Quality Control (EQC) cartridges are used to check instrument operation at two levels
- a Temperature Verification Cartridge (TQC) can be additionally used to check test chamber temperature
- the display is illuminated for viewing in low light
- the user is alerted when the battery is low
- an optional printer can be connected
- Patient/QC test reports can be created using a personal computer and HEMOCHRON *ReportMaker* software

## ATTENTION LABEL

An attention label on the rear of the HEMOCHRON Jr. *Signature* instrument alerts users to accompanying documentation:

Before using the HEMOCHRON Jr. *Signature* instrument, it is essential that the contents of this *Operator's Manual* are read and understood by the operator.

Handle and open the container with care.

### Operator Lockout

A single operator lockout code can be entered into the instrument by use of the HEMOCHRON Jr. Commander Cuvette. If this feature is enabled, only operators with the assigned code can operate the instrument. The code can be changed or disabled by the Supervisor. The operator code is stored in the instrument database and is not printed with test results. See *Setting Operator Lockout Code* on page 13.

### Prewarming

The cuvette is automatically prewarmed to 37 °C ±1.0 °C when it is placed in the test chamber. The instrument will sound one short beep when prewarming is complete.

### Automatic Interrupt

To ensure accurate test results, incubation of a cuvette stops automatically if **START** is not pressed within five minutes after ADD SAMPLE and PRESS START are displayed.

### Test Termination

A test terminates and operation of the test chamber automatically shuts off if clot formation is not detected within a test-specific, preset maximum time.

> ***Note**: Results that are greater than the time noted in the package insert for a test are beyond the sensitivity range of the test. They should be repeated immediately and, if confirmed, reported as greater than the maximum sensitivity range.*

## SPECIFICATIONS

Specifications for the HEMOCHRON Jr. *Signature* Whole Blood Microcoagulation System are listed below.

**Dimensions and Weight**

| | |
|---|---|
| *Depth* | 9 cm (3.5 in) |
| *Width* | 19 cm (7.5 in) |
| *Height* | 5 cm (2.0 in) |
| *Weight* | 0.34 kg (0.7 lbs) |

**Performance**

| | |
|---|---|
| *Test Precision* | ≤ 10% C.V. |

**Operation**

| | |
|---|---|
| *Test Chamber* | 1 |
| *Timing Range* | 0 second to 1,005 seconds |
| *Incubation Temperature* | 37 °C ±1.0 °C |
| *Incubation Warm-Up Time* | 30 seconds to 90 seconds |
| *Full-Charge Operating Time* | 2 to 3 hours (minimum) |
| *Battery Life* | 500 recharges |
| *Battery Type* | Nickel Cadmium |
| *Throughput (Full Charge)* | 49 test cycles (at 150 sec per test) |
| | 17 test cycles (> 500 sec per test) |
| *Operating Environment* | 15 °C to 30 °C |

**AC/DC Power Module**

**USA/Canada**

| | |
|---|---|
| *Input Power* | 120 VAC, 60 Hz, 35 VA |
| *Output Power* | 9.0 VDC, 1.38 Amps maximum |

**Europe**

| | |
|---|---|
| *Input Power* | 230 VAC, 50 Hz, 30 VA |
| *Output Power* | 9.0 VDC, 1.15 Amps maximum |

**Japan**

| | |
|---|---|
| *Input Power* | 100 VAC, 50/60 Hz, 40 VA |
| *Output Power* | 9.0 VDC, 1.3 Amps maximum |

**Calibration**

The *Signature* instrument is calibrated at the manufacturer facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is performed. The instrument does not require additional calibration by the user.

## PREPARING THE INSTRUMENT

### Unpacking and Inspection

***Note**: Inspect each component for damage when unpacking. If damage is observed, contact your shipper or service representative immediately.*

1. Remove any protective packaging that may be present around the instrument.
2. Examine the packaging material to be sure that the power supply and other components have been removed. The materials that are provided are listed below.

   ***Note**: Do not discard the packaging material.*

### Materials Provided

| Article | Quantity |
|---|---|
| HEMOCHRON Jr. *Signature* Microcoagulation Instrument | 1 |
| AC/DC Power Module (see note below) | 1 |
| USA/Canada (ITC Part No. HJ7353) | |
| Europe (ITC Part No. HJ7436) | |
| Japan (ITC Part No. HJ7409) | |
| Electronic System Verification Cartridges (EQC) | 2 |
| Temperature Verification Cartridge (TQC) | 1 |
| Commander Cuvette | 1 |
| Operator's Manual | 1 |

### Materials Required, But Not Provided

| Article | Quantity |
|---|---|
| HEMOCHRON Jr. Test Cuvettes | As Needed |
| HEMOCHRON Jr. Quality Control Products | As Needed |

### Optional Materials

| Article | Quantity |
|---|---|
| HEMOCHRON Jr. PKIT (Printer Kit) | 1 |
| HEMOCHRON Jr. PCKIT (Personal Computer Interface Cable) | 1 |
| HEMOCHRON Jr. CBL-SIG (Serial Printer Interface Cable) | 1 |
| HEMOCHRON *ReportMaker* 4.0 (Data Management Software) | 1 |

***Note:** The AC/DC Power Module that is provided is the one that is appropriate for the country to which the HEMOCHRON Jr. Signature instrument is being shipped. An AC power cord is not provided with the European AC/DC Power Module (ITC Part No. HJ7436).*

### Charging the Battery

The battery of the system should be charged before the system is used.

1. Plug the AC/DC Power Module into an electrical service outlet.

   ***Caution**: Ensure that the input voltage requirements of the AC/DC Power Module match the voltage used in the laboratory.*
2. Connect the AC/DC Power Module cord to the power connector on the side of the instrument.
3. Allow the battery to charge for at least 16 hours.

   ***Note**: The AC/DC Power Module should be disconnected from the instrument when charging is completed.*

**Battery Warning**

The message CHARGE BATTERY is displayed intermittently when the remaining battery power is below a predetermined level.

**Setting the System Time and Date**

The time and date a test is run is saved with the test results. The system time and date can be reset by the operator.

1. Press and hold down the **CANCEL** key.
2. While holding down the **CANCEL** key, insert a cuvette or EQC/TQC.
3. Release the **CANCEL** key when the PRESS START message is displayed.
4. Press the **START** key to display the time:

   TIME: 8:26

5. Enter the new time using the numeric keys.

   ***Note**: Use the 24-hour format (i.e., enter 15:30 for 3:30 pm). The leading zero is required for single digit times (i.e., enter 06:30 for 6:30 am).*

6. Press **ENTER**. The entry is saved, and the date is displayed:

   DATE: 6/01/2004

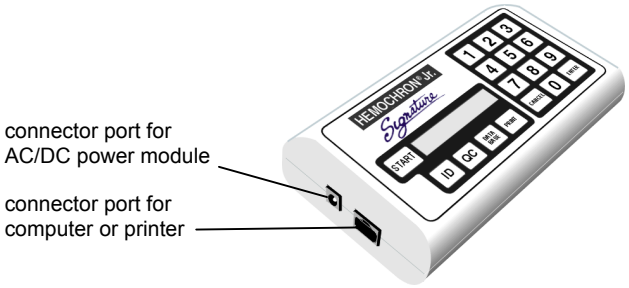
7. Type the new date using the numeric keys.

   ***Note**: The date format is **MM/DD/YYYY**). The leading zero is required for single digit dates (i.e., enter 06/01/2004 for June 1, 2004).*

8. Press **ENTER**. The entry is saved.
9. Remove the cuvette or cartridge to return to normal operation.

**Connecting a Computer or Printer**

An IBM-compatible laboratory computer or a serial printer (Seiko DPU-414 is recommended) can be used with the system. The connector port for these devices is located at the side of the instrument.




**To Connect a Printer:**

1. Obtain a printer interface cable.

   ***Note**: The printer interface cable is included with the optional HEMOCHRON Jr. PKIT (Printer Kit) only. A separate CBL-SIG (Serial Printer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. If a printer is connected, the serial printer communication parameters must be set to 9600 baud with no parity, 8 data bits, and 1 stopbit using XON/XOFF 3-wire software protocol. For additional information on printer configuration, contact ITC Technical Service at **(800) 631-5945** or **(732) 548-5700**, or by e-mail at techservices@itcmed.com.*

2. Connect one end of the cable to the connector port on the side of the instrument.
3. Connect the other end of the printer cable to the printer.

**To Connect a Personal Computer:**

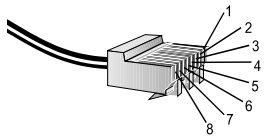
1. Obtain a computer interface cable.

   ***Note:*** *The computer interface cable is not included with the instrument. An optional PCKIT (Personal Computer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. Contact ITC Technical Service for instructions on setting up the personal computer.*

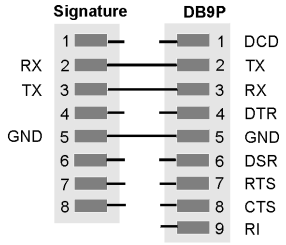
2. Connect one end of the cable to the connector port on the side of the instrument.
3. Connect the other end of the cable to an unused serial communication port on the computer.

**Preparing a Printer or Computer Interface Cable**

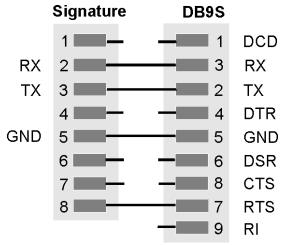
Cabling and connectors can be purchased locally at an electronics store. Use a 6-wire or 8-wire RJ45 to RJ45 modular straight through connecting cable (no longer than 25 feet) plus a RJ45 to DB9 adapter. Numbering of the pins on the RJ45 connectors is shown below:




The cable configurations used for connecting a serial printer or a computer are shown below:



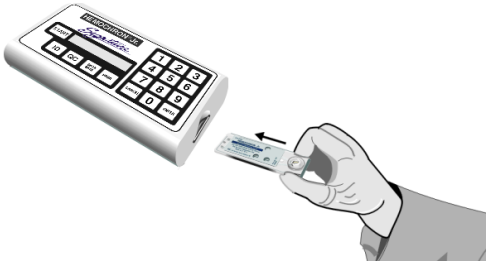

Connecting the instrument to the Seiko DPU-414 printer with a DB9S connector



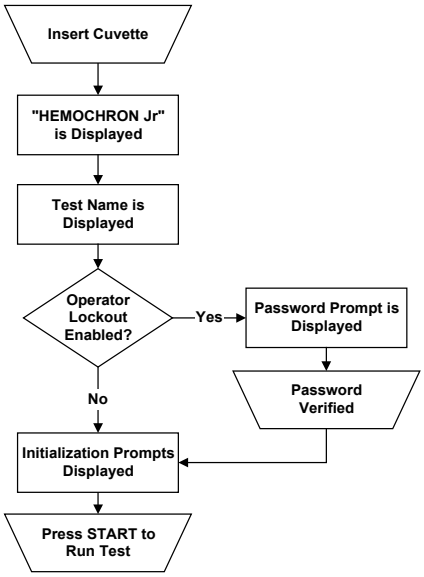

Connecting the instrument to any personal computer with a DB9P connector

## STARTING THE INSTRUMENT

Start the instrument by inserting a cuvette:



***Note**: Insert the cuvette with the label facing up. Push the cuvette all the way in until it stops. Allow cuvettes to reach room temperature (15 to 30 °C) before opening the pouch. This may take up to 60 minutes. Consult the cuvette package insert for additional information concerning cuvette storage and handling.*




When a test cuvette (eg. PT) is inserted to turn on the instrument, the following prompts are displayed:

1) HEMOCHRON Jr
2) Test . . . . . PT
3) Systems…….OK
4) Priming Pump
5) WARMING……...

***Note**: The test name for the inserted cuvette is displayed after **Test.....** . Check the display for fault messages while the cuvette is warming. Refer to the Troubleshooting section for the procedure to resolve a fault message.*

When the cuvette reaches 37 °C ±1.0 °C, the instrument will beep and alternately display:

ADD SAMPLE . . . . . and . . . . . PRESS START

The sample can now be added. After the sample is added, press **START** to run the test.

## SETTING OPERATOR LOCKOUT CODE

The HEMOCHRON Jr. Commander Cuvette can be used to enable operator lockout. If operator lockout is enabled, an operator must enter a code in order to use the instrument.

1. Press and hold down the **1** key.
2. While holding down the **1** key, insert the HEMOCHRON Jr. Commander Cuvette into the instrument.
3. Release the **1** key. A prompt is displayed to enter the code:

   PWD=

4. Type the code, using the numeric keys.

   ***Note:*** *The code can contain up to twelve digits. The code cannot be* ***0*** *(zero).*

5. Press **ENTER**. The entry is saved.

   ***Note:*** *The lockout code can be designated (or changed) at any time. The requirement to enter a lockout code can be disabled by entering* ***0*** *(zero) in Step* ***4*** *or by pressing the* ***ENTER*** *key without entering a number.*

## RUNNING A TEST

Samples are designated as patient samples by default. If a control is being run, the sample type must be changed from **patient sample** to **QC NORMAL** or **QC ABNORMAL**. If a patient sample is being run, this step is unnecessary.

***Important****: Failure to select* ***QC NORMAL*** *or* ***QC ABNORMAL*** *for a control sample will result in storage of the control results as patient results in the patient database.*

1. Insert a test cuvette into the instrument.
2. Press **QC** to display the QC menu:

   1=N 2=Abn 3=PAT

3. Press **1** to designate the sample as a normal control:

   QC NORMAL

   Or press **2** to designate the sample as an abnormal control:

   QC ABNORMAL

   ***Note:*** *Once the QC menu is displayed, the sample type can be selected by pressing the numeric key corresponding to the desired sample type. The sample type can be designated either before or after the test is run, while the test cuvette is still inserted in the instrument. Entry of QC levels cannot be performed while a test is running.*

   ***Note****: To exit the QC menu, press and hold the* ***CANCEL*** *key for three seconds.*

   ***Note****: If any error messages appear on the instrument screen, do not change any previous patient/QC tags. Remove cuvette and repeat test using a new cuvette.*

A numeric Patient ID (PID) and/or Operator ID (OID) can be entered for each test. The IDs will be stored with the results for the test. Entry of a PID and/or OID is optional. When entering an optional PID or OID, any ID (up to twelve digits) can be entered.

**To Enter an Optional Patient ID:**

1. Insert a test cuvette into the instrument.
2. Press **ID** to display the ID menu:

   1=PATIENT 2=OPER

3. Press **1** to enter a numeric PID:

   PID= _. . . . . .

4. Type the PID using the numeric keys.
5. Press **ENTER**. The entry is confirmed as saved.

***Note:*** *The PID can be designated (or changed) before or after a test is run, while the cuvette is in the instrument. If a PID is not entered for a test, the PID is stored as* ***0*** *(zero) in the database.*

**To Enter an Optional Operator ID:**

1. Insert a test cuvette into the instrument.
2. Press **ID** to display the ID menu:

   1=PATIENT 2=OPER

3. Press **2** enter a numeric ID.

   OID= _. . . . . .

4. Type the OID using the numeric keys.
5. Press **ENTER**. The entry is confirmed as saved.

***Note:*** *The OID can be designated (or changed) before or after a test is run, while the cuvette is in the instrument. If an OID is not entered for a test, the OID is stored as* ***0*** *(zero) in the database.*

***Note:*** *Entry of identification numbers cannot be performed while a test is running.*

**Specimen Collection**

Collect blood specimens according to NCCLS document H21-2, entitled *Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays*.

***Important****: Collect blood specimens in a manner that prevents contamination with tissue thromboplastin, indwelling intravenous (I.V.) solutions, or alcohol cleansing solution. Discard samples that are not properly collected or contain visible clots or debris.*

*Use a 23 gauge or larger needle if a syringe is used for blood collection. If a sample is expelled through the same needle, do it slowly to prevent hemolysis.*

*Consult the cuvette package insert for additional information concerning specimen collection and storage.*

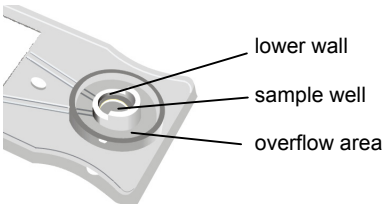
**Starting the Test**

After initialization is completed the instrument beeps once, signaling the instrument is ready for the sample. ADD SAMPLE and PRESS START are displayed, and the blood sample can be placed into the cuvette and the test started.

***Note**: Older versions of the HEMOCHRON Jr. Signature instrument may not recognize newer assays such as Citrate PT and Citrate APTT. In this case, the instrument will display **COD=**. For information on adding new assays to the instrument, contact ITC Technical Service or your ITC sales representative at **(800) 631-5945** or **(732) 548-5700**.*

***Note**: START TIMEOUT is displayed if the test is not started within five minutes. If this occurs, repeat the test using a new cuvette.*

1. Place a drop of blood into the sample well of the cuvette:




***Note**: Fill the sample well from the bottom up. Add enough blood so that the lower wall of the center sample well is completely filled. If the meniscus of the blood sample extends above the lower wall, push the excess blood into the overflow area. A transfer needle can be used to transfer blood.*

2. Press the **START** key. The elapsed time (in seconds) is displayed until the sample clots.

   ***Note**: SAMPLE TOO SMALL, SAMPLE TOO LARGE, or SAMPLE NOT SEEN is displayed if an incorrect amount of sample was added. Repeat the test using a new cuvette.*

3. When a clot is detected, the instrument beeps once. Final results of the test are calculated and displayed.

   ***Note**: The whole blood clotting times are converted to plasma equivalent values (for APTT and APTT Citrate) or plasma equivalent values and International Normalized Ratio (for PT and PT Citrate). Press the **START** key to display the whole blood clotting times (for three seconds). Celite equivalent values are displayed for ACT-LR and ACT+.*

4. Remove the cuvette and discard it.

   ***Note**: Results are saved in the database and printed if a printer is connected. The date and time of the test and the PID/OID (if entered) are printed with the test result.*

**Instrument Shutdown**

If not in use, the instrument will automatically shutdown after five minutes.

## QUALITY CONTROL

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommends that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable performance of the equipment. Complete records of such quality control must be kept.

Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the HEMOCHRON Jr. *Signature* consists of the following operations:

- Testing system performance using Electronic System Verification Cartridges at two levels every eight hours of operation.
- Testing cuvettes in accordance with the Package Insert for each assay using two levels of liquid controls.

**Self-Check**

The HEMOCHRON Jr. *Signature* instrument performs a "self-check" every time it is activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

- Verification of adequate battery power to complete a full test.
- Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
- Verification that the cuvette temperature is warmed to 37± 1.0 ºC. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.
- Verification that the sample is present and is of sufficient size to run test. This insures that the pumps and sample sensing LEDs are functioning properly and that the cuvette is adequately sealed. If these instrument and sample parameters are not appropriate, the test is terminated and an error message displayed.
- Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message is displayed and the test result is not reported.

**QC of Instrument Performance**

The instrument should be tested at two levels once every eight hours of operation. Electronic quality control cartridges (EQC Cartridges) can be used to provide a two-level electronic verification of instrument performance, or liquid quality control products can be used.

**QC Using EQC Cartridges:**

1. Insert the EQC Cartridge into the instrument. Enter an Operator ID (optional) for the test. The instrument will display:

   E-QC ……..Test and ... WARMING

   ***Note**: System verification checks are performed during this process. If a fault is encountered, the instrument will beep several times and display the error message. Refer to the Troubleshooting section for the procedure to resolve an error message.*

2. After a short interval, the instrument will beep once and alternately display:

   Press E-QC …….. and …….. Start Now

3. Press the **Start** button on the EQC Cartridge. The instrument displays the elapsed time (in seconds) until the EQC Cartridge simulates an endpoint.
4. When the EQC Cartridge simulates an endpoint, the instrument beeps twice. Final results of the test are displayed and saved in the database when the cartridge is removed.

   ***Note**: If a printer is connected, the results are printed when the EQC Cartridge is removed.*

5. Compare the displayed time with the acceptable range for the EQC Cartridge. Then remove the EQC Cartridge.
6. Repeat the procedure using the other EQC Cartridge.

**QC Using Liquid Quality Control Products:**

1. Obtain the liquid quality control products.

   ***Note**: HEMOCHRON Jr. Quality Controls are recommended. Refer to the package insert for the liquid quality control products for storage and handling information.*

2. Select QC NORMAL (or QC ABNORMAL) and enter an Operator ID (optional) for the test.

   ***Important**: LQC results will be stored in the patient database if QC NORMAL or QC ABNORMAL is not selected for the test.*

3. Obtain a cuvette for the test to be validated and insert it into the instrument.
4. When ADD SAMPLE and PRESS START are displayed, add the appropriate liquid control sample and run the test in the same manner as for a patient sample.

   ***Note**: If any error messages appear on the instrument screen, do not change any previous patient/QC tags. Remove cuvette and repeat test using a new cuvette.*

**QC of Cuvettes**

Cuvette validation is carried out using the appropriate HEMOCHRON Quality Control Product kit and the test procedure provided.

Acceptable performance ranges for the HEMOCHRON Jr. cuvettes are included with each HEMOCHRON QC product kit. The cause of out-of-range results is likely attributable to test technique, control material, cuvette and/or the instrument.

**Additional Method to Verify Instrument Temperature**

A Quality Control temperature evaluation of the HEMOCHRON Jr. *Signature* instrument is performed automatically each time a test is run (see the Self-Check section on page 16). However, for purposes of your QC program, it may be preferred to additionally perform a temperature QC evaluation using the ITC Temperature Verification Cartridge to verify that a temperature of 37 °C ±1.0 °C is maintained. The Temperature Verification Cartridge can be obtained from ITC.

## OPERATING PRECAUTIONS

The AC/DC Power Module should be plugged into a standard AC outlet to charge the instrument when it is not in use.

DO NOT remove the AC/DC Power Module from the instrument by pulling on the cord. Although the AC/DC Power Module can be left plugged into an AC outlet when the instrument is unplugged, it is recommended that the AC/DC Power Module be unplugged from the AC outlet when it is not being used to charge the instrument.

DO NOT use cuvettes that are past their marked expiration date or which have been improperly stored.

DO NOT force a cuvette into the instrument. If resistance to insertion is encountered, gently remove the cuvette and examine the cuvette slot. Remove any obstruction before attempting further use of the instrument (see *Service and Maintenance* on page 21).

DO NOT use excessive force in pressing the instrument keys.

DO NOT expose the instrument to extreme temperatures (above 37 °C).

DO NOT drop the instrument.

The HEMOCHRON Jr. *Signature* instrument should only be used by healthcare professionals trained and certified in the use of the system and operated in accordance with facility policies and procedures.

All biohazard safety guidelines pertaining to the handling and disposal of human blood should be strictly adhered to when collecting and handing blood specimens and when operating the HEMOCHRON Jr. *Signature* Microcoagulation instrument.

Used HEMOCHRON Jr. test cuvettes should be considered as potentially infectious. They should be handled according to individual institutional policies concerning the disposal of potentially infectious materials.

HEMOCHRON Jr. *Signature* test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any test results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests. Samples with a hematocrit less than 20% or greater than 55% are not recommended, due to an optical density outside the detection level of the HEMOCHRON Jr. *Signature* Microcoagulation instrument.

***CAUTION**: Verify that any third-party connectivity software to be used is compatible with the software version of the HEMOCHRON Signature instrument in use. Transferred data will be lost if third-party connectivity software is used with non-compatible versions of HEMOCHRON Signature software.*

## LIMITATIONS

Test results of the HEMOCHRON Jr. *Signature* Microcoagulation instrument are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the blood specimen, including the blood sample collection and the transfer of blood to the test cuvette. Refer to the individual assay package insert for specific limitations.

## RESULTS MANAGEMENT

Up to 234 patient test results and 85 quality control test results can be stored in the instrument. In addition to test results, the date and time of each test, PID, and OID (if entered) are also stored.

***Note**: PID and/or OID are stored as **0** (zero) if a value is not entered when the test is run. A PID is not required for any QC test.*

**To Print Results:**

1. Insert a test cuvette or EQC/TQC into the instrument.
2. Press **PRINT** to display the Print menu:

   1=LST 2=PAT 3=QC

   Then perform one of the following procedures:

**To Print Results of the Last Test:**

1. Press **1**. Results of the last test are printed.

**To Print All Results in a Database:**

1. Press **2** to print all of the results in the patient database. Or, press **3** to print all of the results in the QC database.

**To Abort Printing of Results:**

1. Pressing **CANCEL** for three seconds will abort data transmission to the printer. Any data previously transmitted will complete printing.

***Note**: Printing of large databases may be interrupted if the cuvette is removed during the printing process.*

### Other Database Operations

The total number of test results that are currently stored and the total number of additional test results that can be stored can be displayed. Also, the results in either the patient database or the quality control database can be erased to make room for additional test results.

***CAUTION**: Results from the oldest test are overwritten if a test is run when the database is full. Therefore, it is important to periodically check, print, archive, and erase the database contents.*

**To Perform Other Database Operations:**

1. Insert a test cuvette or EQC/TQC into the instrument.
2. Press **DATABASE** to display the DATABASE menu:

   1=QUERY 2=ERASE

   Then perform one of the following procedures:

**To Display Total Tests and Remaining Tests in the Database:**

1. Press **1**. The Query menu is displayed:

   1=Patient 2=QC

2. Press **1**. The total number of stored patient records and the number of records that can still be added to the patient database are displayed:

   41 Tests 193 Left

   Or, press **2**. The total number of stored QC records and the number of records that can still be added to the QC database are displayed:

   12 Tests 73 Left

**To Delete All Results from a Database:**

1. Press **2**. The Erase menu is displayed:

   1=Patient 2=QC

2. Press **1** to erase the patient database. (Or, press **2** to erase the QC database.)
3. The instrument displays a prompt to confirm deletion of the database:

   Sure? 1-YES 2-NO

4. Press **1** to confirm deletion. Completed! is displayed for two seconds.

   ***Note**: Press **2** or **CANCEL** to cancel erasing of the database.*

**To Exit Database Operations:**

1. Press and hold **CANCEL** for two seconds.

### Downloading QC/Patient Data to Your PC

For information on downloading QC/Patient data to your PC without *Report Maker* software, contact ITC Technical Service for instructions.

## TROUBLESHOOTING

### Instrument Error Messages

The  error messages that may be displayed while operating the HEMOCHRON Jr. *Signature* instrument are listed below. The probable cause and corrective action are shown for each message.

If needed, contact ITC Technical Service by phone at +1-732-548-5700, by FAX at +1-732-548-9824, or by e-mail at techservice@itcmed.com.

| Error Message | Cause | Corrective Action |
|---|---|---|
| CHARGE BATTERY | Battery power depleted below predetermined level. | Connect to AC/DC Power Module and charge battery for 16 hours. |
| Heater Too Cool | Incubator remained below 36 °C after 90 seconds of warming on external power or for up to 150 seconds on battery. | Repeat test, then charge battery. If message persists, contact ITC Technical Service. |
| Heater Too Hot | Incubator exceeded 38 °C for 2.5 seconds. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |
| Redo, then chrge Heater too cool | Incubator remained below 37 °C after 90 seconds of warming on external power or for up to 150 seconds on battery. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |
| Detector blocked | Light path between LED and detectors is blocked. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |
| Sample Not Seen | Sample has not reached front detector in specified time period. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |
| Cuvette Removed | Cuvette was prematurely removed from instrument while testing in progress. | Repeat test with new cuvette. |
| Sample Too Large/ Sample Too Small | Excess or insufficient sample. | Repeat test with new cuvette. |
| Premature Sample | Sample was detected at front detector before specified time period.  May occur if sample is added before pump-priming sequence is complete. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |
| MEMORY FAULT | Malfunction in the computer's memory. | Contact ITC Technical Service. |
| START timeout | START key was not pressed within 5 minutes after entering ready mode. | Remove cuvette and repeat test with new cuvette. |
| Premature Clot | Sample has clotted prematurely, or did not mix correctly in cuvette. Bubbles may be present. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |

| Error Message | Cause | Corrective Action |
|---|---|---|
| Bubbles, Repeat | Bubbles are present in the sample. | Remove cuvette and repeat test with a new cuvette. |
| Invalid code<br>Invalid cuvette | Invalid cuvette code entered by Operator. | Re-enter information. |
| Use new cuvette | Used cuvette was reinserted into instrument. Occurs if cuvette channel is blocked or if sample is added before pump priming sequence is complete. | Remove cuvette and repeat test with new cuvette. |
| INR< 0.8<br>INR > 10.0<br>APTT < 20<br>Out of Range-Lo<br>Out of Range-Hi | Test result is outside clinical range. | Repeat test with new cuvette. |
| Pump Fault 2<br>Pump Fault 3 | Sample has not reached or departed the rear detector in the specified time. | Repeat test with new cuvette. If message persists, contact ITC Technical Service. |

## SERVICE AND MAINTENANCE

### Routine Maintenance

Inspect and clean the cuvette opening as required. Remove residual dried blood or other foreign matter using water moistened cotton swabs.

Remove any residual water with dry cotton swabs. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe instrument with a water-dampened cloth to removal residual disinfectant from the plastic surfaces.

Apply solution to clean and disinfect areas contaminated with blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components. Routine maintenance other than cleaning normally is not required.

### Service

The HEMOCHRON Jr. *Signature* instrument is almost completely self-monitoring.

It monitors internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages detailed in the *Troubleshooting* section.

### Battery Care

To optimize battery life, it is recommended that the HEMOCHRON Jr. *Signature* instrument be run on its battery during the day. It can be plugged into a standard AC outlet overnight to allow the batteries to recharge. The life of the nickel-cadmium battery is optimized when the battery is exercised in this manner.

A fully charged battery will operate as defined in the *Operation* specifications section on page 8.

When the batteries are drained to the point that valid testing cannot be performed, the instrument will display "CHARGE BATTERY" (see the *Troubleshooting* section). At this point, the instrument must be plugged in for operation and recharging. Once plugged into an AC outlet, the instrument can be used immediately.

### Instrument Disposal

If disposal is necessary, follow local regulations for disposal of electronic devices.

## SAFETY STANDARDS

The HEMOCHRON Jr. *Signature* instrument complies with the following safety standard requirements and directives:

| | |
|---|---|
| **CSA C22.2. 601.1.** | Medical Electrical Equipment – General Requirements for Safety |
| **EN 60601-1** / **IEC 60601-1** | Medical Electrical Equipment – General Requirements for Safety |
| **EN 60601-1-2** / **IEC 60601-1-2**/ **UL 60601-1** | Medical Electrical Equipment – Part 1-2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests |
| **EN 61000-3-2** | Electromagnetic Compatibility – Limits – Limits for Harmonic Current Emissions |
| **EN 61000-3-3** | Electromagnetic Compatibility – Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems |
| **EN 55011** | Industrial, Scientific and Medical (ISM) Radio Frequency Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement |
| **EN 61326** | Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements |
| Directives: 89/336/EEC and as amended by 91/263/EEC, 92/31/EEC, 93/68/EEC, 98/13/EC, and 98/79/EC. | |

All the relevant documentation is kept on file at ITC in Edison, NJ.

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